

## REMARKS

### Status of Claims

Claims 1-7 and 14-23 are currently pending in the present application. Claims 1 and 6 are amended. Support for the amendment to Claim 1 can be found in the specification, for example, at paragraphs [0058], [0108], and [0109]. Claim 6 was amended to clarify its language. Thus, no new matter is introduced. Accordingly, Claims 1-7 and 14-23 are presented for examination on the merits.

### Drawings

Applicants respectfully request the Examiner to acknowledge acceptance of the drawings filed on May 14, 2007.

### Rejections under 35 U.S.C. § 102(b) based on Fukuda

#### Claims 1-6 and 14-23

The Examiner has rejected Claims 1-6 and 14-23 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,136,580 to Fukuda et al. ("Fukuda"). A claim is anticipated only if each and every element of the claim is expressly or inherently found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP § 2131.

According to the Examiner, Claims 1-6 and 14-23 only recite two active steps comprising (1) detecting core-2  $\beta$ 1,6-N-acetylglucosaminyltransferase in a sample and (2) analyzing the sample. *Office Action* of April 16, 2010 at page 4. Moreover, the Examiner did not give weight to the "wherein" clause of Claim 1 allegedly because it merely states the results of the two active steps of the claim. *Id.* at page 5. With this interpretation, the Examiner concluded that Fukuda at column 14, line 62 – column 15, line 66 reads on those two active steps. *Id.* The cited portion of Fukuda describes use of an antibody to detect C2GnT-M in a sample, but does not disclose what the sample is or what use the antibody is for other than detection of C2GnT-M or targeting cells that express C2GnT-M. For the reasons discussed below, Applicants respectfully disagree with the Examiner's analysis.

As an initial matter, Applicants point out that the foregoing rejection does not apply to Claims 17-23, which comprise *three* active limitations including providing a biological sample

from the subject; contacting the biological sample with an antibody having specificity for core-2  $\beta$ 1,6-N-acetylglucosaminyltransferase polypeptides; and determining whether the antibody binds to the core-2  $\beta$ 1,6-N-acetylglucosaminyltransferase polypeptides at a higher level than normal controls, wherein a higher level of binding is indicative of an increased risk for cancer recurrence.

Although the cited portion of Fukuda describes use of an antibody to detect C2GnT-M in a sample, it does not disclose that the sample is a cancer tissue, much less the ability of one to predict the recurrence of cancer based on determining whether the antibody binds to the core-2  $\beta$ 1,6-N-acetylglucosaminyltransferase polypeptides at a higher level than normal controls, wherein a higher level of binding is indicative of an increased risk for cancer recurrence. Accordingly, Claims 17-23 clearly include three active limitations, including particularly “determining whether the antibody binds to the core-2  $\beta$ 1,6-N-acetylglucosaminyltransferase polypeptides at a higher level than normal controls.” This is not taught either directly or inherently by Fukuda. Thus, Fukuda does not anticipate Claims 17-23 and Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b).

Claim 1 has been amended similar to previously presented Claim 17 to comprise *three* active limitations including detecting the level of core-2  $\beta$ 1,6-N-acetylglucosaminyltransferase polypeptides in a sample collected from a biological organism; comparing the level to a normal control level; and detecting an increased risk for recurrence of cancer if a higher level of core-2  $\beta$ 1,6-N-acetylglucosaminyltransferase polypeptides compared to normal is found.

As discussed above, the cited portion of Fukuda does not disclose comparing the level of C2GnT-M to a normal control level, much less detecting an increased risk for recurrence of cancer if a higher level of core-2  $\beta$ 1,6-N-acetylglucosaminyltransferase polypeptides compared to normal is found. Accordingly, Fukuda fails to disclose each and every limitation of amended Claim 1 and the claims dependent therefrom. Thus, Applicants request withdrawal of the rejections of Claims 1-6 and 14-16 under 35 U.S.C. § 102(b).

#### **The Pending Claims are Non-obvious over the Cited Art**

The pending claims are directed to a new use for an antibody that detects C2-GnT polypeptides. The Applicants discovered that cancer recurrence can be detected or predicted by

**Application No.:** 10/549,811  
**Filing Date:** September 14, 2006

the claimed inventive methods prior to commencing unnecessary medical treatments such as tissue resection or other therapy. The claimed methods provide information as to whether it is medically necessary or advantageous to proceed with a particular therapeutic course of action. For example, by allowing cancer recurrence to be detected or predicted, the inventive methods can guide an informed therapeutic course of action, including whether cancer tissue resection or total tissue resection is recommendable relative to the risk of cancer recurrence, or whether a need to select another therapy exists.

By contrast, the cited art merely discloses an antibody against C2-GnT-M. Disclosure of the antibody alone could not predictably lead to the inventive methods of detecting or predicting cancer recurrence, which provide useful information for choosing a therapeutic course before unnecessary treatment or surgery is undertaken. As such, Applicants submit that pending Claims 1-7 and 14-23 are non-obvious over the cited art.

### **Conclusion**

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. In light of the above amendments to Claim 1 and remarks concerning the remaining pending claims, Applicants respectfully request issuance of a Notice of Allowance. If the Examiner has any questions which may be answered by telephone, the Examiner is invited to call the undersigned directly.

### **No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not

**Application No.:** 10/549,811  
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reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: June 16, 2010

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